

What is claimed is:

1. A method for determining the presence of an analyte in urine sample, comprising the steps of:

providing a conjugate pad comprising a chromogenic mobile specific binding partner for an analyte;

5 providing a chromatographic test strip comprising a matrix through which a urine test sample can flow by capillarity wherein said chromatographic test strip comprises at least two reaction sites;

a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of the analyte in the urine sample; and

a control reaction site comprising a specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner;

contacting said conjugate pad to said chromatographic test strip such that said first reaction site lies between said conjugate pad and said control reaction site;

contacting said chromatographic test strip with an absorbent pad such that said absorbent pad is positioned opposite said conjugate pad and such that both said first reaction site and control reaction site lie in-between said conjugate pad and said absorbent pad;

developing said chromatographic test strip by applying urine sample suspected of containing said analyte thereto thereby allowing the same to contact said chromogenic mobile specific binding partner to form an analyte/chromogenic mobile specific binding partner complex whereby capillarity carries the urine test sample along the strip to the first reaction site containing said immobilized specific binding reagent and said control reaction site comprising said specific binding partner;

determining the presence of analyte in the urine test sample by detecting the presence of chromogenic complex at said first reaction site;

determining if migration has occurred by detecting the presence of chromogenic complex at said control reaction site; wherein detection may be made by observation of color at the control reaction site.

2. The method of claim 1 further comprising a second reaction site positioned in-between said first reaction site and said control reaction site capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of whole antibody in said urine.
3. The method of claim 1 wherein said analyte is selected from the group consisting of free kappa chains, free and bound kappa, free lambda, and free and bound lambda.
4. The method of claim 1 wherein said urine sample is untreated urine.
5. The method of claim 1 wherein said mobile specific binding partner is at least one conjugated monoclonal antibody.
6. The method of claim 1 wherein said chromogenic mobile specific binding partner is selected from the group consisting of conjugated anti-free and bound kappa antibody and conjugated anti-free and bound lambda antibody.
7. The method of claim 1 wherein said immobilized specific binding reagent is selected from the group consisting of free kappa, free and bound kappa, free lambda, free and bound lambda for performing a competitive analysis.
8. The method of claim 1 wherein said immobilized specific binding reagent is selected from the group consisting of anti-free kappa antibody and anti-free lambda antibody.
9. The method of claim 1 wherein said specific binding reagent is Protein A for the detection of immunochemicals.
10. The method of claim 1 wherein said second reaction site comprises a second specific binding reagent selected from the group consisting of anti-free

and bound kappa antibody and anti-free and bound lambda antibody for the determination of the presence of whole antibody.

11. The method of claim 1 wherein said assay is a sandwich assay and the step of determining the presence of analyte in urine further comprises visualization of a band at said first and second reaction site.

12. The method of claim 1 wherein the step of determining the presence of analyte in urine further comprises visualization of said first and said control reaction site, wherein the absence of band formation at said first reaction site indicates a positive result and the visualization of a band at said first reaction site indicates a negative result and wherein the visualization of band formation at said control reaction site indicates that the test has worked in competitive assay.

13. A device for the detection of analyte in urine comprising:

a conjugate pad said conjugate pad comprising a chromogenic mobile specific binding partner capable of binding to an analyte;

a chromatographic test strip comprising a matrix through which urine can pass by capillarity carrying said mobile specific binding partner and said analyte, wherein said chromatographic test strip comprises three reaction sites,

a first reaction site comprising an immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of the analyte in the urine sample,

a second reaction site comprising a second immobilizing specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of the analyte in the urine sample,

a third control reaction site comprising a third immobilizing specific binding partner capable of immobilizing said mobile specific binding partner in relation to the capillary action transporting said chromogenic mobile specific binding partner through said chromatographic test strip;

an absorbent pad disposed upon said chromatographic test strip such that said absorbent pad is positioned opposite said conjugate pad and such

20 that said first reaction site, second reaction site, and said third reaction site lie in-between said conjugate pad and said absorbent pad.

14. The device of claim 13 wherein said urine is untreated human urine.

15. The device of claim 13 wherein said analyte is selected from the group consisting of free kappa chains, free and bound kappa, free lambda, and free and bound lambda.

16. The device of claim 13 wherein said chromatographic test strip is a porous material.

17. The device of claim 13 wherein said chromatographic test strip is nitrocellulose or nylon.

18. The device of claim 13 wherein said chromogenic mobile specific binding partner is at least one conjugated monoclonal antibody.

19. The device of claim 13 wherein said chromogenic mobile specific binding partner is a conjugated monoclonal antibody cocktail.

20. The device of claim 13 wherein said chromogenic mobile specific antibody is selected from the group consisting of conjugated anti-free and bound kappa antibody and conjugated anti-free and bound lambda antibody.

21. The device of claim 13 wherein said immobilized specific binding reagent is anti-free kappa antibody.

22. The device of claim 13 wherein said third immobilizing specific binding partner is Protein A.

23. The device of claim 13 wherein said second immobilizing specific binding reagent is selected from the group consisting of anti-free and bound

kappa antibody and anti-free and bound lambda antibody for the determination of the presence of whole antibody.

24. The device of claim 13 wherein the presence of analyte in urine is determined by visualization of a band at said first and second reaction site.

25. The device of claim 13 wherein the visualization of the control reaction site indicates that immunological chemicals have migrated through said chromatographic test strip.

26. A test strip for the determination of an analyte in urine comprising:
a backing member;

a chromatographic test strip disposed upon said backing member said chromatographic test strip comprising a matrix through which a urine sample can flow by capillarity wherein said chromatographic test strip comprises at least two reaction sites,

a first reaction site comprising an immobilized specific binding reagent capable of immobilizing a chromogenic mobile specific binding partner in relation to the presence of the analyte in the urine sample; and

a second reaction site comprising a specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner.

27. The test strip of claim 26 wherein said urine is untreated human urine.

28. The test strip of claim 26 wherein said chromogenic mobile specific binding partner is selected from the group consisting of free kappa, free and bound kappa, free lambda, free and bound lambda.

29. The test strip of claim 26 wherein said first immobilized specific binding reagent is selected from the group consisting of free kappa, free and bound kappa, free lambda, free and bound lambda.

30. The test strip of claim 26 wherein said specific-binding reagent is Protein A.

31. The test strip of claim 26 wherein said analyte is selected from the group consisting of free light chains and classes thereof.
32. The test strip of claim 26 wherein the presence of analyte in urine is determined by the absence of band formation at the first reaction site.
33. A kit for determining the presence of an analyte in urine comprising;
the test strip of claim 26; and
a reaction tube for mixing said test strip with an aliquot of urine.
34. The kit of claim 33 wherein said reaction tube delivers between 100 microliters of urine to 1.0ml preferably 300 microliters of urine to said test strip.
35. The kit of claim 33 wherein said reaction further comprising a cap for facilitating disposal of biological waste.
36. A kit for determining the presence of an analyte in urine comprising;
the device of claim 13; and
a reaction tube for contacting aliquots of urine to said device.
37. The kit of claim 36 wherein said aliquot of urine is an amount within the range of 100 microliters of urine to 1.0ml preferably 300 microliters of urine.
38. The kit of claim 36 wherein said reaction further comprising a cap for facilitating disposal of biological waste.